MAY 2 2 2012 3

3.0 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Applicant:

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Date Prepared: April 23, 2012

Device Information:

Trade Name:	Amphirion™ Plus PTA Catheter
Common Name:	Percutaneous Transluminal Angioplasty Catheter
Regulation Name:	Percutaneous Catheter
Classification:	Class II
Classification Panel:	Peripheral
Regulation Number:	21 CFR 870.1250
Product Code:	DQY

Predicate Devices:

Amphirion™ DEEP 0.014" OTW PTA Balloon Catheter (K052791 SE-11/04/2005)

REEF HP 0.035" OTW PTA Balloon Dilatation Catheter (K092361 SE-10/29/2009)

Submarine™ Plus PTA Catheter (K042537 SE-11/08/2004)

Device Description:

The Amphirion Plus PTA Catheter (also referred to as Amphirion Plus) is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter consisting of a proximal hub, coaxial body catheter shaft, and a distal dilatation balloon. The Amphirion Plus device consists of a coaxial lumen. The lumen marked "WIRE" is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum diameter of 0.014". The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the balloon. Two radiopaque marker bands are placed under the balloon segment of the catheter shaft to provide visual reference points for balloon positioning within the vessel. The Amphirion Plus PTA Catheter is compatible with guidewires with a maximum diameter of 0.014" and with 4F introducer sheaths. The catheter is provided with a hydrophilic coating and is available in useable catheter lengths of 100cm and 150cm.

Indications for Use:

The Amphirion Plus PTA Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The indications for use for the Amphirion Plus PTA Catheter is identical to the currently cleared predicate devices, Amphirion DEEP PTA Balloon catheter (Amphirion DEEP), REEF HP PTA Balloon Catheter (REEF HP) and the Submarine Plus PTA Catheter (Submarine Plus).

Technological Characteristics:

The Amphirion Plus PTA Catheter is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter. The overall design and the fundamental scientific technology of the Amphirion Plus device is equivalent to the currently cleared predicate devices, Amphirion DEEP PTA Balloon catheter, REEF HP PTA Balloon Catheter and the Submarine Plus PTA Catheter. Description of the modified device, Amphirion Plus PTA Catheter, is provided in the table below:

Characteristic	Modified Amphirion Plus PTA Catheter
Balloon Lengths (mm)	A shorter balloon length of 14mm was added to the Amphirion Plus balloon size matrix. The 14mm balloon is made of identical materials and manufacturing processes as the other balloon sizes.
Catheter Useable Length (cm)	The Amphirion Plus catheter useable lengths are within the Amphirion DEEP and REEF HP catheter useable lengths.
Catheter Shaft Diameter	The Amphirion Plus catheter shaft diameters are within the Amphirion DEEP and REEF HP catheter shaft diameters.

Characteristic	Modified Amphirion Plus PTA Catheter
Catheter Shaft Material	The Amphirion Plus catheter shaft material is identical to the material used on the Amphirion DEEP device.
Nominal Pressure (ATM)	Identical to REEF HP
Rated Burst Pressure (ATM)	Amphirion Plus PTA Catheter has a Rated Burst Pressure (RBP) of 20 ATM for all the balloon sizes. This RBP is within the REEF HP RBP range of 18-22 ATM.
Balloon Material	Amphirion Plus Balloon Material is identical to the Submarine Plus PTA Catheter balloon material.

Medtronic believes that the Amphirion Plus PTA Catheter is substantially equivalent to the above mentioned predicate devices, in terms of indications for use, design, material and fundamental scientific technology. Therefore, in accordance with "*The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications (March 1998)*", the Amphirion Plus PTA Catheter does not affect the intended use or alter the fundamental scientific technology of the device and meets the criteria for a Special 510(k) Pre-Market Notification.

Summary of Bench Testing:

The Amphirion Plus PTA Catheter was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications. The bench testing plan was developed based on the risk assessment of the device modifications, and the recommendations outlined in the applicable FDA guidance documents, ISO and ASTM standards. Testing performed on the Amphirion Plus device included the following:

- Catheter Useable Length
- Introducer Sheath Compatibility
- Trackability-Flexibility-Kink test
- Torque Strength
- Catheter Body Burst Pressure
- Tensile Strength
- Balloon Inflation/Deflation Time
- Balloon Preparation
- Balloon Profile
- Balloon Working Length
- Minimum Balloon Burst Strength (RBP)
- Balloon Fatigue
- Balloon Compliance

All of the pre-determined acceptance criteria were met and results passed.

Summary of Biocompatibility Testing:

The Amphirion Plus PTA Catheter is an externally communicating device, which contacts circulating blood for the limited contact duration (<24hours).

Biocompatibility testing was conducted on the finished Amphirion Plus PTA Catheter in accordance with ANSI/AAMI/ISO10993-1: *Biological Evaluation of Medical Devices part 1: Evaluation and Testing*, FDA 21 CFR Part 58: *Good Laboratory Practice for Non Clinical Laboratory Studies* and FDA guidance: *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters* (Sept 2010). The Biocompatibility testing performed for the Amphirion Plus device included the following:

- ISO MEM Elution Cytotoxicity Test
- ISO Kligman Maximization Test
- ISO Intracutaneous Reactivity Study
- ISO Acute Systemic Toxicity Study
- ISO Material Mediated Rabbit Pyrogen Study
- ASTM Indirect contact - Hemolysis
- ISO Thrombogenicity Study
- ISO Indirect contact – Complement activation

All of the pre-determined acceptance criteria were met and results passed.

Assessment of non-clinical performance data for equivalence:

Bench and biocompatibility testing of the Amphirion Plus PTA Catheter was performed in accordance with the relevant FDA guidance, ISO and ASTM standards. Results from these non-clinical testing demonstrates that the Amphirion Plus PTA Catheter met the pre-determined acceptance criteria and performs comparably to the predicate devices. No new safety or effectiveness issues were observed during the testing.

Conclusion:

Based on the same indications for use, design, material, fundamental scientific technology and performance characteristics, the Amphirion Plus PTA Catheter is substantially equivalent to the predicate devices, Amphirion DEEP, REEF HP and Submarine Plus PTA Balloon Catheter. Results from the non-clinical performance testing demonstrate that the Amphirion Plus PTA Catheter is safe, effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 2 2012

Medtronic Vascular
c/o Ms. Nainesh Sureja
3576 Unocal Place
Santa Rosa, CA 95403

Re: K121265
Trade/Device Name: Amphirion Plus PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: April 25, 2012
Received: April 25, 2012

Dear Ms. Sureja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Statement of Indications for Use

Indications for Use

510(k) Number (if known): K121265

Device Name: Amphirion™ Plus PTA Catheter

Indications For Use:
The Amphirion™ Plus PTA Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121265